E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0461; FRL-10016-23]

Sethoxydim; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of sethoxydim in or on basil, dried leaves and basil, fresh leaves. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2019-0461, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to

provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in

40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2019-0461 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2019-0461, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of October 3, 2019 (84 FR 52850) (FRL-9999-89), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E8769) by IR-4, IR-4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The

petition requested that 40 CFR 180.412 be amended by establishing tolerances for residues of the herbicide sethoxydim, including its metabolites and degradates, determined by measuring only the sum of sethoxydim, 2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one (CAS Reg. No. 74051-80-2) and its metabolites containing the 2-cyclohexen-1-one moiety, calculated as the stoichiometric equivalent of sethoxydim, in or on basil, dried leaves at 20 parts per million (ppm) and basil, fresh leaves at 8 ppm. That document referenced a summary of the petition prepared by IR-4, the petitioner, which is available in the docket for this action, docket ID number EPA-HQ-OPP-2019-0461, at *http://www.regulations.gov*. No relevant comments were received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

A. Statutory Background

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but it does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of sethoxydim and to make a determination on aggregate exposure for sethoxydim, including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with sethoxydim follows.

B. Sethoxydim Aggregate Risk Assessment

On June 15, 2015, EPA published in the *Federal Register* a final rule establishing tolerances for residues of sethoxydim in or on multiple commodities based on the Agency's conclusion that aggregate exposure to sethoxydim is safe for the general population, including infants and children. *See* 80 FR 34070 (FRL-9928-20) (Docket ID EPA-HQ-OPP-2014-0161). In an effort to streamline *Federal Register* publications, EPA is not reprinting here summaries of its analysis that have previously appeared in the *Federal Register* in tolerance rulemakings for the same pesticide. To that end, this rulemaking refers the reader to the following sections from the June 15, 2015 tolerance rulemaking for sethoxydim that remain unchanged for an understanding of the Agency's rationale in support of this rulemaking: Units III.A (Toxicological Profile); III.B. (Toxicological Points of Departure/Levels of Concern); III.C. (Exposure Assessment), except as explained in the next paragraphs; III.D. (Safety Factor for Infants and Children); and IV.A (Analytical Enforcement Method).

1. *Updates to exposure assessment*. EPA's dietary (food and drinking water) exposure assessments have been updated to include the additional exposure from the new use of sethoxydim on basil. In addition, the acute dietary exposure assessment was revised to: (1) assume 100% crop treated, instead of using percent crop treated as described in the 2015 rule; and (2) incorporate empirical and/or EPA's 2018 default processing factors. The assumption of tolerance-level residues for both the acute and chronic dietary analyses has not changed. For the chronic dietary exposure assessment, EPA incorporated updated average crop treated estimates for select commodities and EPA's 2018 processing factors.

The new use on basil does not impact drinking water exposures; therefore, the Agency relied on the same values for drinking water exposures as expressed in the June 2015 rulemaking.

While EPA has updated the human equivalent doses for assessing inhalation risk to residential handlers, this revision does not impact the approach of the aggregate assessment. The

scenario and life stage resulting in the highest residential exposures for use in the aggregate assessment and which is considered protective of other exposure scenarios continues to be the post-application incidental oral hand-to-mouth exposure of children (1 to less than 2 years old) on treated turf. The new use on basil does not result in any additional residential exposures.

2. *Assessment of aggregate risks*. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose and chronic population adjusted dose. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

Acute dietary (food and drinking water) risks are below the Agency's level of concern of 100% of the acute population adjusted dose (aPAD): they are less than 12% of the aPAD for children 1 to 2 years old, the population subgroup with the highest exposure estimate. Chronic dietary risks are below the Agency's level of concern of 100% of the chronic population adjusted dose (cPAD): they are 24% of the cPAD for children 1 to 2 years old, the population subgroup with the highest exposure estimate.

For the aggregate risk assessment, exposures to sethoxydim in food and drinking water are combined with residential exposures for the relevant exposure duration period. Aggregate acute and chronic risk are equivalent to the dietary risks, which are below EPA's level of concern, because neither acute nor long-term residential exposures are expected.

The short-term aggregate risk assessment considers only residential incidental oral exposures and combines chronic (background) exposures with the expected short-term post-application exposures to children 1 to 2 years old. This yields an MOE of 4,400, which is not of concern because it exceeds EPA's level of concern (MOEs less than or equal to 100). Intermediate-term residential exposures are not expected.

Finally, as stated in the June 2015 rulemaking, sethoxydim is not expected to pose a cancer risk to humans.

C. Determination of Safety

Therefore, based on the risk assessments and information described and referenced above, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to sethoxydim residues. More detailed information about the Agency's analysis can be found in "Sethoxydim: Human Health Risk Assessment to Support the Section 3 Use on Basil and a Label Amendment to Reduce the Pre-harvest Interval for Caneberry Subgroup 13-07A" dated October 21, 2020 in docket ID number EPA-HQ-OPP-2019-0461.

IV. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

The Codex has not established a MRL for sethoxydim.

V. Conclusion

Therefore, tolerances are established for residues of sethoxydim, including its metabolites and degradates, determined by measuring only the sum of the herbicide 2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one (CAS Reg. No. 74051-80-2) and its metabolites containing the 2-cyclohexen-1-one moiety, calculated as the stoichiometric equivalent of sethoxydim, in or on basil, dried leaves at 20 ppm and basil, fresh leaves at 8 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition

submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with

Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq*.), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 5, 2020.

Marietta Echeverria,
Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.412, amend paragraph (a) by designating the table and adding in alphabetical order in newly designated Table 1 to paragraph (a) the entries "Basil, dried leaves" and "Basil, fresh leaves" to read as follows:

§ 180.412 Sethoxydim; tolerances for residues.

(a) * * *

Table 1 to Paragraph (a)

Commodity	Parts per million
* * * * * * *	
Basil, dried leaves	20
Basil, fresh leaves	8
* * * * * * *	

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[FR Doc. 2020-26014 Filed: 12/2/2020 8:45 am; Publication Date: 12/3/2020]